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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,862	02/27/2002	Steffen Schlehuber	029029-0101	3214
22428	7590	08/26/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,862	Applicant(s) SCHLEHUBER, STEFFEN	
	Examiner Samuel W Liu	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 1,3 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-27-02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 1-17 are pending.

Applicant's amendment filed 7 December 2001, which amends claims 3, 5-8, 13, 15 and 17 has been entered. Also, applicant's request (filed 6 May 2002) for extension of time of one month has been entered.

Note that, however, there is an ambiguity in the applicant's amendment filed 7 December 2001 because the amendment states "cancel the second claim 15" which is unclear as to what is "the second claim 15, and meanwhile the amendment sets forth the amended claim 15. The corresponding clarification in this regard is required.

To advanced prosecution, Examiner considers claim 15 to be a pending claim.

Election/restriction

Applicants' election of Group I, claim 1-7 in the response filed 28 June 2004 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, the pending claims 1-7 are examined in this Office action. Claims 8-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

IDS

The references cited in the IDS filed 27 February 2002 have been considered by Examiner.

Foreign priority

Acknowledgment is made of applicant's claim for foreign priority based on a Germany patent application No.199 26 068, filed 8 June 1999. It is noted, however, that applicant has not filed a translated copy of the Germany 199 26 068.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

The first paragraph of the specification should indicate continuing data or/and foreign priority of the current application, i.e., insert the following paragraph before the "Description" paragraph:

This application is a 371 of PCT/DE00/01873 filed 8 June 2000, which claims foreign priority benefit of the filing date under 35 U.S.C. 119 of Germany patent application No.199 26 068, filed 8 June 1999.

In page 26, line 14, " $1 \cdot 10^{12}$ and $5 \cdot 10^{12}$ cfu/ml" should be changed to " 1×10^{12} and 5×10^{12} cfu/ml".

In the page 26, "DMSO" should be spelled out in full for the first instance of use. See also page 27, line 11, "DMF".

In claim 1, a comma "," should be inserted between "4-aminofluorescein" and "and (c) has".

In claim 3, "selected from" should be changed to "selected from the group consisting of".

In claim 5, "selected from" should be changed to "selected from the group consisting of".

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Appropriate correction is required.

Claim Rejection under 35 USC 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 and the dependent claims, as written, do not sufficiently distinguish over polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed polypeptide and the naturally occurring polypeptides. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite in not identifying the claimed bilin-binding protein with SEQ ID NO. _ because, without “SEQ ID NO. _”, the recited amino acid substitution in item *c* of claim 1 renders the claim indefinite. Claim 1, item *c*, recites “substitutions at at least one of the sequence positions”; the recitation is indefinite because of (a) tandem terms “at at”; and (b) unclearness of “the sequence positions”; does it refer to sequence identifiers or *amino acid positions*? Claim 1 recites “a polypeptide selected from muteins of the bilin-binding protein, characterized in that ...”; the recitation is not clear because it ambiguously refers to (i) “mutein (i.e., a mutational form) of the bilin-binding protein characterized in ...; and (ii) said bilin-binding protein (i.e., non-mutational form) characterized in... . Further, claim 1, item *c*, is not apparent in “the bilin-binding protein” because it not clear as to whether or not said bilin-binding protein is a wild type protein, i.e., not a mutein (a mutational form) of the bilin-binding protein. The dependent claims are also rejected.

Claim 2 recites the limitation “the complex”. There is insufficient antecedent basis for this limitation in claim 1 from which claim 2 depends. Also, claim is indefinite in the limitation “100 nM or less” because the term “less” ambiguously extends the limitation to an indefinite value; does said “less” encompass zero?

Claim 3 is unclear in “in comparison with the bilin-binding protein”. What is in the comparison? is non-mutational form of the bilin-binding protein in said comparison, or, is *other* mutein (i.e., mutational form) of the wild-type bilin-binding protein compared? Also, claim 3 is indefinite in not identifying the bilin-binding protein with SEQ ID NO. _ because, without “SEQ ID NO. _”, the recited amino acid substitutions render the claim indefinite.

Claim 4 is indefinite because SEQ ID NO:15 is a polynucleotide sequence but not the amino acid sequence as recited in the claim.

Claim 5 appears to set forth a Markush group; yet, the claim contains an open ended Markush group because “or” is set forth before the last component of the Markush group, which is open-ended. Note that Markush group requires close language. Suggest “and” before “metals or colloidal gold”. Additionally, claim 5 is not apparent in “(bio) luminescent label”; does it refer to biological or biochemical luminescent label, or, non-biological luminescent label.

Claim 6 recites “fusion protein of polypeptide according to claim 1”; the recitation is unclear as to whether or not (i) said fusion protein of claim 1, or (ii) the polypeptide of claim 1; which one is it? Also, claim 6 is not apparent in “another protein”; is said “another protein” the other type of mutin of the bilin-binding protein recited in claim 1, or any otherwise protein? In addition, claim 6 recites “in an operable manner”; the recitation is vague regarding whether or not it refers to operable in protein folding (e.g., folding of one fusion partner will promote another’s folding), or operable in protein or enzymatic activity, or operable in recognition by a specific protease, which cleaves the conjugation peptide sequence between the two fusion partners. Further, claim 6 recites “or/and”; the recitation renders the claim indefinite because it is unclear as to how many components participate in the fusion protein. Do all the components, i.e., (i) an enzyme, (ii) another protein or a protein domain, (iii) a signal peptide sequence and (iv) an affinity peptide, are fused? See also claim 7.

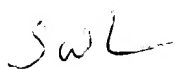
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Claim 7 is unclear in the recitation "targeting sequence". The specification provides insufficient definition for this recitation. Also, claim 7 recites "or/and"; the recitation is indefinite because it is unclear as to how many components participate in the fusion protein. Which one is it, "or" or "and"? Do all the components, i.e., (i) an enzyme, (ii) another protein or a protein domain, (iii) a targeting sequence and (iv) an affinity peptide, are fused?

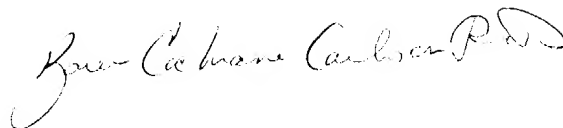
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner
August 7, 2004



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER